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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/789,558 | 02/27/2004 | Brendan M. Donohoc | 151 | 9249 |
| 33109 | 7590 | 02/26/2007 | EXAMINER | |
| CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063 | | | YABUT, DIANE D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/789,558 | DONOHOE ET AL. | |
| | Examiner | Art Unit | |
| | Diane Yabut | 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 12-14 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 12-14 and 21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/10/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This action is in response to applicant's amendment received on 20 November 2006. The examiner acknowledges the corrections made to the specification and the amendments of the claims, as well as the cancellation of claims 10-11, 15-20.

Claim Rejections - 35 USC § 112

1. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 12 recites "a single control operationally connected to both the cutting device and the graft vessel attachment device" on lines 7-8, but the specification is silent as to the actuation of the two devices by a single control.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobis et al.** (U.S. Patent No. 6,605,098) in view of **Vargas et al.** (U.S. Patent No. 6,673,088).

Claims 1, 9, and 12: Nobis et al. discloses the claimed device, including a tool body having an aperture at a distal end thereof, a substantially hollow chamber (a compartment or cavity as seen in Figure 1) and an introducer positioned at a distal end of the chamber and having a lumen open to the chamber, the introducer configured to substantially seal against the target vessel, whereby the chamber substantially maintains hemostasis, a cutting device 600 movably attached to the tool body and positioned at least partially in the tool body and having a distal end configured to form the opening in the target vessel ("first vessel" or "first hollow organ"), at least the distal end of the cutting device movable through the aperture, and a graft vessel attachment device 200 movably attached to the tool body and positioned at least partially in the tool body and having a distal end configured to connect the graft vessel to the target vessel, at least the distal end of the graft vessel attachment device movable through the aperture, wherein connect the graft vessel to the target vessel wherein the cutting device is movable to a position within the chamber after forming the opening in the target vessel, and a single control operationally connected to both the cutting device and the graft attachment device ("a single control" can be interpreted as the surgeon, as he/she operates the device of Nobis) (see Figures 1, 10, 12, 15a-b and col. 2, lines 13-21, col. 6, lines 42-67, col. 8, lines 1-14 and 34-62), except for the cutting device also being movable linearly substantially

along a first direction (longitudinally) and transversely to the first direction, or a second path or direction, and wherein the graft attachment device is movable linearly along a second direction, wherein both the first and second directions are angled relative to the longitudinal direction. Although only the cutting device is movable at a direction angled relative to the longitudinal direction, it would have been obvious to one of ordinary skill in the art at the time of invention to provide both instruments with the ability to be translated at an offset axis so as not to interfere with each other's functions and deployment/retraction.

Vargas et al. teaches a tissue punch for creating a hole in the wall of a target blood vessel wherein the cutting device is movable along a first direction along the axis of the tissue punch tool body and also transverse to the first direction, or along a second path or direction (Figures 1-5). Vargas et al. teaches that the cutting element moves in first and second directions in order to punch a hole in the target vessel and then to allow the anastomosis device to be deployed through the lumen of the tool body (col. 4, lines 63-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a cutting device movable along first and second directions, as taught by Vargas et al., to Nobis et al. in order to make way for another device, such as an anastomosis device, to be deployed through the tool body.

Claim 13: Nobis et al. discloses the device being configured to form the opening without passing the cutting device or the graft vessel attachment device through a lumen of the graft vessel (Figure 12 and col. 9, lines 13-51).

Claim 14: Nobis et al. discloses the device delivering and deploying the implantable anastomosis device without passing the cutting device or the graft vessel attachment device through a lumen of the graft vessel (col. 7, lines 25-37 and col. 10, lines 46-60).

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobis et al.** (U.S. Patent No. **6,605,098**) and **Vargas et al.** (U.S. Patent No. **6,673,088**), as applied to Claim 1 above, and further in view of **Killion et al.** (U.S. Patent No. **5,921,957**).

Claim 2: Nobis et al. and Vargas et al. disclose the claimed device except for the introducer being splittable.

Killion teaches an introducer ("tip") being splittable in order to accommodate wider diameter instruments to be inserted through the introducer (col. 5, lines 4-15). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a splittable introducer, as taught by Killion et al., to Nobis et al. and Vargas et al. in order to accommodate larger instruments to be inserted through the introducer.

4. Claims 3, 4, 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Houser** (U.S. Pub. No. **20020173808**).

Claims 3 and 6: Houser discloses a tool body **200** having a lumen, a cutting device **204** configured to form the opening in a target vessel, the cutting device being movable at least partially within the lumen, and a graft vessel attachment

device **238** movable at least partially within a lumen for delivering the implantable anastomosis device to the target vessel to connect the graft vessel to the target vessel, wherein the cutting device is movable away from the axial centerline of the lumen (Figures 21a-21c, 22, 26; page 11, paragraphs 126 and 132).

Although Houser does not disclose both the graft vessel attachment device and the cutting device are contained within the lumen of the tool body simultaneously, Houser does disclose a tool body having dual mechanism integrated within in Figure 22 (see page 3, paragraph 45 and page 11, paragraph 126) that punctures a vessel wall and advances a sheath into the vessel, and it would have been obvious to one of ordinary skill in the art to provide both a cutting device and a graft vessel attachment device into one tool body since it was known in the art that multiple devices in one tool body provides convenience and more controllable movement of each device and efficiently performs anastomosis.

Claim 4: Houser discloses a cutting device **600** includes a substantially circular cutting element, in that it has a diameter (Figure 21a).

Claim 7: Houser discloses an introducer connected to the tool body, the introducer having a lumen substantially coaxial with the lumen of the tool body (Figure 21a).

Claim 8: Houser discloses the tool body including an off-axis area defined therein, and wherein at least one member of the group, consisting of the graft vessel attachment device and the cutting device, is configured to move away from the axial centerline of the lumen into the off-axis area, or a second path, and discloses the graft vessel attachment device being movable substantially along

the first direction, or first path axial along the centerline of the lumen, wherein the first path and the second path form a Y-shape and intersect (Figures 21a-21c).

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over by **Houser** (U.S. Pub. No. **20020173808**) as applied to Claim 3 above, and further in view of **Sirimanne et al.** (U.S. Patent No. **6,136,014**).

Claim 5: Houser discloses the claimed device except for the cutting device including an auger.

Sirimanne et al. teaches a cutting device **168** including an auger **166** that is helpful in separating the excised tissue from the cutting surface and the remaining tissue and maintains the integrity and continuity of the removed tissue (Figure 4A and col. 7, lines 27-40). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an auger, as taught by Sirimanne et al., to Houser in order to efficiently separate excised tissue from remaining tissue from the cutting surface.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobis et al.** (U.S. Patent No. **6,605,098**) and **Vargas et al.** (U.S. Patent No. **6,673,088**), as applied to Claim 9 above, and further in view of **Daniel** ((U.S. Patent No. **6,622,731**).

Claim 21 (new): Nobis et al. and Vargas et al. disclose the claimed device except for a pivotable introducer connected to the distal end of the tool body wherein the aperture is located in the introducer.

Daniel teaches a pivotable introducer connected to the distal end of the tool body wherein the aperture is located in the introducer (Figure 4). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pivotable introducer, as taught by Daniel, to Nobis et al. and Vargas et al since it was known in the art that the mechanism provides more flexibility in manipulating devices and that are allowed to reach inaccessible areas in the body.

Response to Arguments

7. Applicant's arguments filed 20 November 2006 have been fully considered but they are not persuasive.

8. Regarding Claims 1-2, Applicant generally argues that Nobis et al. does not disclose each and every element claimed in Claim 1, such as a substantially hollow chamber that substantially maintains hemostasis. The examiner disagrees, in that Figure 1 has a hollow chamber, which is interpreted as the compartment into which 200 is placed, and the distal end of the tool body (proximal to 110) is a blunt surface considered to maintain hemostasis (also see col. 2, lines 13-17), and therefore it is maintained that Nobis et al., Vargas et al., and Killion et al. read on every element, as mentioned above for Claims 1 and 2.

The examiner considers

9. Regarding Claims 9 and 21, Applicant generally argues that Nobis fails to disclose linear motion of the cartridge and the punch in two different directions, each angled relative to the longitudinal direction, although it is maintained above

that the punch does have angular motion relative to the longitudinal direction, and that it would have been obvious to one of ordinary skill in the art at the time of invention to provide both instruments with the ability to be translated at an angled direction with respect to the longitudinal axis, so as not to interfere with each other's functions and deployment/retraction and to eliminate instrument exchanges (also see col. 2, lines 18-21).

10. Regarding Claims 12-14, Applicant generally argues that Nobis et al. does not disclose a single actuation for the cutting device and the graft vessel attachment device, even though Applicant's specification is silent as to a single control that controls both devices. In an event, Nobis et al. does read on the limitation, as mentioned above, if "single control" is interpreted as the user who actuates the device of Nobis to manipulate both devices.

11. Applicant's arguments with respect to Claims 3-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



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